

Remarks

Claims 1-19 are pending. Claim 20 was previously cancelled.

Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Itoi, U.S. Patent No. 6,159,437 in view of Kumta et al., U.S. Patent No. 7,247,288.

The Examiner has indicated that claims 14-19 are allowed.

Claim 1 has been amended to clarify that the claimed composition is a colloidal dispersion of calcium phosphate platelets wherein the length of the platelets, *L*, is between 5 and 500 nm and the thickness of the platelets is between 0.5 and 20 nm, and at least one polymer which complexes calcium. No new matter is added.

The applicant respectfully maintains that the Examiner has failed to establish a *prima facie* case of obviousness in this case. The references cited by the Examiner, when read in their entirety from the perspective of one skilled in the art, do not describe, teach or suggest all of the limitations recited in claims 1-19 as amended.

Scope and Content of the Cited Art

Itoi, U.S. Patent No. 6,159,437 describes an apatite slurry comprised of apatite particles which are dispersed in a water compatible organic solvent and which has a degree of dispersion such that the average particle size of the apatite particles is 1 μm or less and particles of 3 μm or less are “practically absent”. Col. 1, lines 7-14. Itoi describes a slurry of apatite particles which are aggregates of apatite crystal particles. Itoi states that “[g]enerally, apatite particles are formed by aggregation of such primary particles to a size of about 10 μm to 100 μm .” Col. 3, lines 33-35.

The primary particles described in Itoi are “apatite crystal particles with a short axis length of 10 to 100 nm and a long axis length of 30 to 300 nm.” Col. 3, lines 26-27. According to Itoi, these apatite crystal particles form larger particles of 10 μm to 100 μm in diameter. It is these larger particles that are dispersed in a water soluble organic solvent to form the apatite slurry described by Itoi. The larger particles are suspended and dispersed in the water-compatible organic solvent and the resulting slurry is dispersed using an agitation mill to achieve the final dispersion. Col. 4, lines 33-59. A dispersion agent, such as sodium hexametaphosphate or sodium tripolyphosphate, may be added to the slurry. Col. 3, lines 53-57. As shown in Table 1 and the figures of Itoi, all of the slurries described in Itoi include substantial amounts of particle apatite having particle size larger than 500 nm.

In the Office Action, the Examiner responds that the particle size of 10 μm to 100 μm are the particle size before agitation milling. While this may be so, the final dispersion described by Itoi after agitation milling includes a substantial quantity of apatite particles having dimensions greater than 500 nm. As shown in Figure 2 of Itoi, about 30% of the apatite particles of the composition of example 2 have particle size over 500 nm. In addition, the slurries described in Table 1 all have maximum particle sizes of at least 970 nm (0.97 μm), which is plainly greater than the claimed maximum size of 500 nm. In addition, as acknowledged by the Examiner, Itoi does not describe or suggest complexing the calcium phosphate particles with a polymer.

Kumta, U.S. Patent No. 7,247,288, describes a method for producing nanocrystalline hydroxyapatite particles having a diameter in the range of about 1 nm to about 100 nm. Col. 8, lines 19-22. Kumta also describes incorporating the hydroxyapatite particles produced from the process into a substrate or depositing the hydroxyapatite particles on a substrate. Col. 8, lines 44-49. The substrate may be a “matrix, such as a biomimetic extracellular matrix, which is

synthetic matrix that is intended to mimic a natural extracellular matrix in its structure and/or function.” Col. 8, lines 49-53. Kumta states that the matrix may be a natural or synthetic polymer. Col. 8, lines 53-55.

The hydroxyapatite described by Kumta is not present in a colloidal dispersion. In describing the incorporation of the hydroxyapatite with the extracellular matrix, Kumta states that the hydroxyapatite is associated with or incorporated in the matrix by adding the hydroxyapatite to the matrix polymer during polymerization or cross-linking. Col. 8, line 44 to col. 9, line 2. The resulting material is illustrated in Fig. 11 of Kumta, which clearly shows hydroxyapatite particles that are embedded within the polymer matrix.

Kumta does not teach the use of a polymer to complex the apatite to form a colloidal dispersion. Rather, Kumta describes certain polymers that may be used to form a biomimetic extracellular matrix. Kumta further describes incorporating hydroxyapatite in the extracellular matrix by adding hydroxyapatite to the polymer used to form the extracellular matrix during polymerization or cross-linking. As illustrated in Fig. 11 of Kumta, the resulting material comprises hydroxyapatite particles within the polymer matrix, and it does not describe a colloidal dispersion at all. Indeed, while Kumta describes incorporating formed apatite particles in the extracellular matrix, in the colloidal dispersion of the present application, the polymer that complexes calcium is added to the solution used to form the hydroxyapatite before the heat treatment stage in which the hydroxyapatite is formed. Kumta does not teach or suggest use of a polymer that complexes calcium in a colloidal dispersion.

The Examiner responds that Kumta describes use of a hydroxyapatite-nucleic acid complex in an ointment, balm or lotion. Use of a hydroxyapatite-nucleic acid complex in a

carrier vehicle is not a colloidal dispersion of the hydroxyapatite, much less a dispersion of hydroxyapatite having calcium complexed with a polymer.

In order to establish a prima facie case of obviousness, the combined references must describe all of the limitations of the claimed invention. Itoi does not describe a colloidal dispersion of calcium phosphate particles having the particle size distribution recited in claim 1. Kumta does not describe a colloidal dispersion of calcium phosphate particles at all. Accordingly, the colloidal compositions recited in claims 1-13 are not obvious in view of the combination of Itoi and Kumta for at least this reason.

Moreover, neither Itoi nor Kumta describe or suggest a polymer complexed to the calcium in the calcium phosphate material as an aid to form the colloidal dispersion. Accordingly, the composition of claims 1-13 is not obvious in view of Itoi and Kumta for this additional reason.

In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, and in particular if a terminal disclaimer is required for allowance, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections.

Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Petition for a One Month Extension of Time and the associated fee is filed herewith. This paper is filed on December 21, 2009, the first business day after December 19, 2009, which was a Saturday. No additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

Dated: December 21, 2009

Respectfully submitted,



Eric E. Grondahl
Registration No. 46,741
Attorney for Applicants

PTO Correspondence Address:
McCarter & English LLP
City Place I
185 Asylum Street
Hartford, CT 06103
(860) 275-6704 - Phone
(860) 724-3397 - Fax